CNS, Inc. 7615 Smetana Lane Eden Prairie, Minnesota 55344 phone [952] 229 1500 fax [952] 229 1700

MAY 1 7

May 5, 2005

The Breathe Right Company

Food & Drug Administration Center for Food Safety and Applied Nutrition Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) 5100 Paint Branch Parkway College Park, MD 20740

Subject:

Notification of Structure/Function Claims, Dietary Supplement

CNS, Inc., Minneapolis, MN 55439

FiberChoice® Plus Calcium and FiberChoice® Bone Health Formula

This letter shall serve as a notification for the use of structure/function claims in the labeling and advertising of a dietary supplement in accordance with 21 CFR 101.93. CNS, Inc. uses the structure/function claims on the following pages with the dietary supplements FiberChoice® Plus Calcium chewable tablets and FiberChoice® Plus Calcium drops, and FiberChoice® Bone Health Formula chewable tablets and FiberChoice® Bone Health Formula drops. The dietary ingredients of interest are fiber in the form of inulin and calcium in the form of calcium carbonate. All products contain 4 grams of inulin and 500 milligrams of calcium in a dose.

These claims will be accompanied by the following disclaimer upon the next printing of labels and labeling material.

"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This information is complete and accurate. CNS has substantiation that these statements are truthful and not misleading. If you have any questions, please feel free to contact me at the numbers provided below.

Sincerely,

978 0162 LET 16173

Director of Quality Assurance and Product Development

Phone (Direct): 952.229.1595

Fax: 952.229.1700

E-mail: gfenton@cns.com

FiberChoice® Plus Calcium and FiberChoice® Bone Health Formula Comprehensive List of Claims

Note: The list of claims is submitted for the following product names. The products contain 4 grams of inulin and 500 mg of calcium per dose. Either of the following names will be used on the products, but only the name FiberChoice[®] Plus Calcium will be used in the listing.

- FiberChoice® Plus Calcium
- FiberChoice® Bone Health Formula

CALCIUM ABSORPTION

FiberChoice® Plus Calcium contains inulin fiber — a proven way to help your body absorb calcium.**

FiberChoice® Plus Calcium contains a proven way to help your body absorb calcium.**

FiberChoice® Plus Calcium helps your body absorb calcium.**

FiberChoice® Plus Calcium with inulin fiber to help your body absorb calcium.**

FiberChoice® Plus Calcium contains inulin fiber to help your body absorb calcium.**

FiberChoice® Plus Calcium is made with inulin fiber — a proven way to help your body absorb calcium.**

FiberChoice® Plus Calcium contains a proven way to help your body absorb calcium.**

FiberChoice® Plus Calcium contains inulin fiber to help your body absorb calcium.**

FiberChoice® Plus Calcium contains inulin fiber — a proven way to help boost calcium absorption.**

FiberChoice® Plus Calcium contains a proven way to help boost calcium absorption.**

FiberChoice® Plus Calcium helps your body boost calcium absorption.**

FiberChoice® Plus Calcium with inulin fiber to help boost calcium absorption.**

FiberChoice® Plus Calcium helps boost calcium absorption.**

CALCIUM ABSORPTION

(continued)

FiberChoice® Plus Calcium contains inulin fiber to help boost calcium absorption!**

FiberChoice® Plus Calcium — made with inulin fiber to help boost calcium absorption.**

FiberChoice® Plus Calcium — Proven better absorption.**

FiberChoice® Plus Calcium — Proven increased absorption.**

FiberChoice® Plus Calcium — Easy to take, proven better absorption.**

FiberChoice® Plus Calcium delivers better calcium absorption**

FiberChoice® Plus Calcium delivers increased calcium absorption.**

FiberChoice® Plus Calcium gets more calcium where it needs to go.**

(Note: the claims above would be footnoted to the statement below)

BONE AND TEETH HEALTH

FiberChoice® Plus Calcium helps maintain good bone health

FiberChoice® Plus Calcium helps maintain strong, healthy bones

RiberChoice® Plus Calcium helps keep your bones healthy and strong

FiberChoice® Plus Calcium — for better bone health

FiberChoice® Plus Calcium helps build and maintain healthy bones and teeth

FiberChoice® Plus Calcium promotes good bone health

FiberChoice® Plus Calcium helps build better bones and teeth

FiberChoice® Plus Calcium helps build stronger bones and teeth

FiberChoice® Plus Calcium — for healthy bones

FiberChoice® Plus Calcium — for healthier bones and teeth

FiberChoice® Plus Calcium helps build healthier bones and teeth

FiberChoice® Plus Calcium helps strengthen bones and teeth

FiberChoice® Plus Calcium helps build strong bones

FiberChoice® Plus Calcium helps build stronger bones

FiberChoice® Plus Calcium — Good for your bones

FiberChoice® Plus Calcium — Good for your bones and teeth

FiberChoice® Plus Calcium — a good source of calcium

FiberChoice® Plus Calcium is good for your bones

FiberChoice® Plus Calcium is good for your bones and teeth

FiberChoice® Plus Calcium is a good source of calcium to help keep bones healthy and strong.

FiberChoice® Plus Calcium — because calcium in a healthy diet is essential for good bone health, especially in teen and adult women

BONE AND TEETH HEALTH (continued)

FiberChoice® Plus Calcium provides calcium that is essential for good bone health, especially in teen and adult women

FiberChoice® Plus Calcium provides the calcium that is essential for good bone health, especially in teen and adult women

COMBINED BENEFIT

FiberChoice® Plus Calcium promotes good digestive health while it helps build strong bones

FiberChoice[®] Plus Calcium promotes good digestive health while it helps keep bones healthy and strong

FiberChoice[®] Plus Calcium — inulin fiber for good digestive health and calcium to keep bones healthy and strong

FiberChoice® Plus Calcium promotes good digestive health while it helps build strong bones and teeth

FiberChoice[®] Plus Calcium promotes good digestive health while it helps build and maintain strong bones.

FiberChoice® Plus Calcium promotes good digestive health while it helps build and maintain strong bones and teeth

FiberChoice® Plus Calcium — inulin fiber for good digestive health and calcium for healthy bones

FiberChoice[®] Plus Calcium — inulin fiber for good digestive health and calcium for healthy bones and teeth

FiberChoice[®] Plus Calcium is an excellent source of calcium for strong bones and fiber for good digestive health.

FiberChoice® Plus Calcium can be important to your overall health. Inulin fiber promotes good digestive health while calcium helps build healthier bones.

FiberChoice® Plus Calcium can be important to your overall health. Inulin fiber promotes good digestive health while calcium helps strengthen bones and teeth

FiberChoice® Plus Calcium contains calcium for healthy bones and teeth plus inulin fiber for good digestive health and improved calcium absorption.**

FiberChoice® Plus Calcium contains calcium for healthy bones and teeth plus inulin — a calcium absorption booster and a good source of daily fiber.**

FiberChoice[®] Plus Calcium contains calcium for strong bones plus inulin — a calcium absorption booster and a good source of daily fiber. **

COMBINED BENEFIT

(continued)

FiberChoice[®] Plus Calcium contains calcium for healthy bones and teeth plus inulin — a calcium absorption booster and an excellent source of daily fiber.**

FiberChoice® Plus Calcium

- · Promote's good digestive health and regularity
- Enhances your immune system
- · Helps control weight by making you feel fuller longer
- · Develops stronger bones and teeth

FiberChoice® Plus Calcium

- Promotes good digestive health and regularity
- Enhances your immune system
- Helps control weight by making you feel fuller longer
- · Keeps bones healthy and strong

FiberChoice® Plus 'Calcium — contains inulin fiber for good digestive health and maximum calcium absorption ** and calcium for healthy bones and teeth

FiberChoice[®] Plus Calcium — contains calcium for healthy bones and inulin fiber for good digestive health and maximum calcium absorption**

FiberChoice® Plus Calcium promotes

- healthy digestive system
- · healthy bones and teeth
- overall good health

FiberChoice® Plus Calcium promotes

- · good digestive health
- · healthy teeth and bones
- enhanced immune system

FiberChoice® Plus Calcium

A healthy combination of calcium for stronger bones and teeth and inulin fiber, which promotes overall health and helps boost calcium absorption**

Dietary fiber and calcium, like that found in FiberChoice® Plus Calcium, are important parts of your overall good health.

COMBINED BENEFIT

(continued)

Dietary fiber and calcium, like that found in FiberChoice® Plus Calcium, are important parts of your overall long-term health.

FiberChoice® Plus Calcium

- More fiber per dose
- Enhanced calcium absorption**

FiberChoice® Plus Calcium

- More fiber per dose
- Improved calcium absorption**

FiberChoice® Plus Calcium

- More fiber per dose
- Proven better absorption.**

FiberChoice® Plus Calcium

- More fiber per dose
- Proven better absorption.**

FiberChoice® Plus Calcium

- More fiber per dose
- Proven increased absorption.**

FiberChoice[®] Plus Calcium Helps build and maintain good bone health. Helps promote good overall health.

FiberChoice[®] Plus Calcium For strong bones and teeth For healthy bodies

FiberChoice® Plus Calcium — for strong bones and teeth and overall good health

FiberChoice® Plus Calcium

Because growing bodies need strong bones and teeth and a healthy digestive system

FiberChoice[®] Plus Calcium helps kids build strong bones and teeth and promotes good overall health

FiberChoice® Plus Calcium helps kids build strong bones and teeth and promotes good digestive health and regularity

WEIGHT CONTROL

If you have too little calcium in your diet, you're more likely to gain weight. And the inulin fiber in FiberChoice® Plus Calcium can help you control weight by making your feel fuller longer.

FiberChoice[®] Plus Calcium can help you keep your weight under control. It contains inulin fiber which can help curb cravings by making you feel full longer. And calcium has been shown to fight body fat.

FiberChoice® Plus Calcium can help you control your weight. Calcium may help by increasing the amount of fat your body uses for fuel. And inulin fiber can help curb cravings by making you feel full longer.

FiberChoice[®] Plus Calcium can help you control your weight. People who have too little calcium in their diets are more likely to gain weight. And FiberChoice Plus Calcium is an excellent way to help you get the calcium you need. And the inulin fiber found in FiberChoice Plus Calcium has been shown to help you curb cravings by making you feel full longer.

FiberChoice® Plus Calcium can help you control your weight.**

FiberChoice® Plus Calcium can help you maintain a healthy weight.**

**Inulin (a natural dietary fiber) can help control weight by helping you feel full faster. The calcium in FiberChoice[®] Plus Calcium may help by increasing the amount of fat your body uses for fuel.

OVERALL HEALTH/IMMUNE SYSTEM

FiberChoice® Plus Calcium contains inulin fiber to help restore and maintain beneficial intestinal flora and calcium to help build strong bones and teeth

FiberChoice® Plus Calcium is an excellent source of calcium.

FiberChoice® Plus Calcium helps enhance your immune system and build strong bones

FiberChoice® Plus Calcium — Important parts of your overall health

FiberChoice® Plus Calcium — Important for your overall health

FiberChoice® Plus Calcium. — Essential ingredients for good health

FiberChoice® Plus Calcium can provide essential ingredients for good health.

FiberChoice® Plus Calcium provides essential ingredients for good health.

FiberChoice® Plus Calcium — An important part of your healthy life

FiberChoice® Plus Calcium — An important part of your healthy lifestyle

FiberChoice® Plus Calcium — Essential ingredients of your healthy life

FiberChoice® Plus Calcium — Essential ingredients of your healthy lifestyle

FiberChoice® Plus Calcium — Essential ingredients of a healthy life

FiberChoice® Plus Calcium — Essential ingredients of a healthy lifestyle

FiberChoice® Plus Calcium can be important to your overall health.

FiberChoice® Plus Calcium - a good source of essential ingredients for long-term good health

FiberChoice® Plus Calcium - a good source of essential ingredients for your overall good health

FiberChoice[®] Plus Calcium – a good source of essential ingredients important to your overall health.

FiberChoice® Plus Calcium can be important for your overall health.

FiberChoice® Plus Calcium can be an important part of your healthy life

FiberChoice® Plus Calcium can be an important part of your healthy lifestyle

OVERALL HEALTH/IMMUNE SYSTEM (continued

FiberChoice® Plus Calcium is an excellent source of calcium.

FiberChoice® Plus Calcium – important building blocks for overall good health

FiberChoice® Plus Calcium – important building blocks for long-term good health

FiberChoice® Plus Calcium contains important building blocks for long-term good health

FiberChoice® Plus Calcium contains important building blocks for your overall good health

FiberChoice® Plus Calcium – essential ingredients for long-term good health

FiberChoice® Plus Calcium – essential ingredients for your overall good health

FiberChoice® Plus Calcium – essential ingredients for your long-term good health

BLOOD SUGAR LEVELS

- "Inulin helps keep normal blood sugar levels more uniform."
- "Inulin found in FiberChoice[®] Plus Calcium helps keep normal blood sugar levels more uniform."
- "FiberChoice® Plus Calcium helps keep normal blood sugar levels more uniform."
- "Soluble fiber found in FiberChoice® Plus Calcium helps keep normal blood sugar levels more uniform."
- "Inulin helps keep blood sugar levels that are in the normal range more uniform."
- "Inulin found in FiberChoice® Plus Calcium helps keep blood sugar levels that are in the normal range more uniform."
- "FiberChoice® Plus Calcium helps keep blood sugar levels that are in the normal range more uniform."
- "Soluble fiber found in FiberChoice® Plus Calcium helps keep blood sugar levels that are in the normal range more uniform."

EVERYONE NEEDS FIBER AND CALCIUM

FiberChoice® Plus Calcium — Fiber and calcium are important for overall good health, no matter who you are or what your age

FiberChoice® Plus Calcium — Fiber and calcium are essential for overall good health, no matter who you are or what your age

FiberChoice[®] Plus Calcium Helps you get the fiber and calcium you need at every stage of life

FiberChoice® Plus Calcium
Helps everyone get the fiber and calcium they need at every stage of life

FiberChoice[®] Plus Calcium Helps you get the fiber and calcium you need throughout your life

FiberChoice® Plus Calcium
Helps you get the fiber and calcium everyone needs

FiberChoice® Plus Calcium is an excellent source of soluble fiber and highly absorbable calcium

FiberChoice® Plus Calcium — An excellent source of soluble fiber and highly absorbable calcium